

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

removing a restraint that holds said puncturing element in a retracted position, [moving] said puncturing element automatically moving in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element when said restraint is removed [such that said puncturing element punctures the vessel wall at the site to be treated with the puncturing element; and

delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall].

4
2. (once amended) The method of claim [1] ~~21~~ ³ wherein the step of delivering the drug comprises delivering the drug into the vessel wall.

A'
5
3. (once amended) The method of claim [1] ~~21~~ ³ wherein the step of delivering the drug comprises delivering the drug to the outer surface of the vessel wall.

6
4. (once amended) The method of claim [1] ~~21~~ ³ wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.

7
5. (once amended) The method of claim [1] ~~21~~ ³ wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.

8
6. (once amended) The method of claim [1] ~~21~~ ³ wherein the delivery means includes said puncturing element having a drug delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.

7. (once amended) A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:

an elongated catheter adapted to be inserted into the vessel; said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

a restraint holding said puncturing element in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

said puncturing element automatically moving from said retracted position to said puncturing position when said restraint is released; and

delivery means coupled to said catheter for delivering a drug outside the inner surface of the vessel wall through a puncture in the vessel wall.

2
-- 30. (new) The method of claim 1 further comprising the step of puncturing the vessel wall with the puncturing element at the site to be treated. --

3 2
-- 31. (new) The method of claim 30 further comprising the step of delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall.--

A2
Sub C7
-- 32. (new) A method of treating a vessel having a vessel wall with an inner surface, the method comprising the steps of:

inserting a catheter having a vessel puncturing element disposed therein into a substantially tubular vessel;

positioning the puncturing element at the site in the vessel to be treated;

applying an adjacent force adjacent said puncturing element to move said puncturing element in a direction substantially non-parallel with respect to a portion of said catheter that contains said puncturing element, said adjacent force moving said puncturing element from a retracted position to a puncturing position.

¹⁸
-- ~~33~~. (new) The method of claim ¹⁷~~32~~ further comprising the step of puncturing the vessel wall with the puncturing element at the site to be treated with the puncturing element. --

¹⁹
-- ~~34~~. (new) The method of claim ¹⁸~~33~~ further comprising the step of delivering via a delivery means a drug outside of the inner surface of the vessel wall through the puncture in the vessel wall.

^{A2}
-- ~~35~~. (new) The method of claim 32 wherein said adjacent force is supplied by inflating an inflatable compartment adjacent said puncturing element.--

^{Sub C8}
-- 36. (new) The method of claim 35 wherein said compartment inflates a predetermined amount to move said puncturing element a predetermined distance. --

²⁰
-- ¹⁹~~37~~. (new) The method of claim ~~34~~ wherein the step of delivering the drug comprises delivering the drug into the vessel wall. --

^{Sub C9}
-- 38. (new) The method of claim 32 wherein the step of applying said force moves said puncturing element a predetermined distance such that said drug is delivered to the outer surface of the vessel wall.--

-- 39.(new) The method of claim 32 wherein the step of delivering the drug comprises delivery of the drug into tissue surrounding the vessel wall.--

-- 40.(new) The method of claim 32 wherein the step of delivering the drug comprises the step of delivering a drug in a time release module.--

--41.(new) The method of claim 32 wherein the delivery means includes said puncturing element having a drug delivery lumen and wherein the step of delivering the drug comprises delivering the drug through the drug delivery lumen.--

--42.(new) A drug delivery device for treating a vessel having a vessel wall with an inner surface, the device comprising:
an elongated catheter adapted to be inserted into the vessel;
said catheter comprising a puncturing element having a retracted position in which said puncturing element does not puncture said vessel wall, at least a portion of said puncturing element being housed in a portion of said catheter when said puncturing element is in said retracted position;

said puncturing element further having a puncturing position in which said puncturing element engages and punctures said vessel wall, said puncturing element being substantially non-parallel with respect to said portion of said catheter when said puncturing element is in said puncturing position;

a movable surface adjacent said puncturing element to contact and move said puncturing element from said retracted position to said puncturing position when said movable surface is moved toward said puncturing element.--

--43.(new) The device of claim 42 wherein said movable surface is part of an inflatable compartment, and said movable surface is moved toward said puncturing element by inflating said inflatable compartment.--

⁴⁰
--~~44~~. (new) The device of claim ³⁸~~42~~ further comprising delivery means coupled to said catheter for delivering a drug outside the inner surface of the vessel wall through a puncture in the vessel wall.--

⁴¹
--~~45~~. (new) The device defined in claim ⁴⁰~~44~~ wherein:
said puncturing element further comprises a puncturing tip for puncturing said vessel wall when said puncturing element is in said puncturing position; and

said catheter further comprises a window through which said puncturing tip extends when said puncturing element is in said puncturing position. --

Sub C10
A2
--~~46~~. (new) The device defined in claim 44 wherein said catheter further comprises:
an inflatable balloon coupled to said catheter; and
an inflation lumen extending through said catheter for delivering inflation fluid to said balloon.--

⁴³
--~~47~~. (new) The device defined in claim ⁴⁰~~44~~ wherein:
said puncturing element further comprises an elongated shaft having a proximal and a distal end and an inner shaft lumen, and a needle, attached to said distal end of said shaft, having an inner needle lumen which is in fluid communication with said inner shaft lumen; and

said delivery means comprises said inner shaft lumen and said inner needle lumen.--

⁴⁴
--~~48~~. (new) The device defined in claim ⁴³~~47~~ wherein said needle further comprises a puncturing tip for engaging and puncturing said vessel wall when said puncturing element is in said puncturing position.--

⁴⁵
--~~49~~. (new) The device defined in claim ⁴⁴~~48~~ wherein said puncturing tip includes an opening in communication with said inner

needle lumen so that fluid in said inner needle lumen can flow out of said tip opening.--

Sub C11
--50.(new) The invention defined in claim 49 wherein said delivery means further comprises an injection device coupled to said inner shaft lumen for injecting fluid through said inner shaft lumen.--

⁴⁷
--~~51~~.(new) The device defined in claim ⁴⁶~~50~~ wherein said puncturing tip has a beveled edge for puncturing said vessel wall.-

⁵⁶
--~~52~~.(new) The device defined in claim ³⁸~~42~~ wherein said puncturing element comprises a needle having a tip for puncturing said vessel wall.--

A2 Sub C12
-- 53.(new) The method of claim 44 wherein said drug comprises an antiproliferative drug for the treatment of restenosis.--

-- 54.(new) The method of claim 44 wherein said drug comprises an antiproliferative drug for the treatment of vascular disease.--

-- 55.(new) The method of claim 44 wherein said drug comprises a specific inhibitor of cellular proliferation.--

-- 56.(new) The method of claim 44 wherein said drug comprises a specific inhibitor of thrombin.--

-- 57.(new) The method of claim 44 wherein said drug comprises a specific inhibitor of platelets.--

-- 58.(new) The method of claim 44 wherein said drug comprises a genetic material.--

A2 -- 59.(new) The method of claim 44 wherein said drug comprises a genetic material that when incorporated into cells results in the expression of therapeutic materials.--

-- 60.(new) The method of claim 44 wherein said drug is incorporated into a time released matrix.--
